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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rodney Carroll on September 30, 2010.

The application has been amended as follows:

1. (Currently Amended) A process for the preparation of sertraline hydrochloride Form V consisting essentially of:

- a. suspending/dissolving sertraline acetate in suitable solvents to form a mixture;
- b. adjusting the pH of said ~~the~~ mixture to a value of from 1 to 2 with aqueous hydrogen chloride at a temperature of about 25°C;
- c. stirring the mixture produced in step (b) at about 25°C; and
- d. isolating and drying under vacuum to obtain sertraline hydrochloride Form V.

2-13. (Canceled)

14. (Previously Presented) A process according to claim 1, wherein the sertraline acetate is suspended/dissolved in a solvent selected from the group consisting of methanol, ethanol, isopropanol, ethyl acetate, water and mixtures thereof.

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15. (Previously Presented) A process according to claim 14, wherein the solvent used is water.

16. (Canceled)

17. (Currently Amended) A process for the preparation of sertraline hydrochloride Form V consisting essentially of:

- a. suspending/dissolving sertraline base in acetic acid to form a mixture;
- b. adjusting the pH of ~~said~~ the mixture to a value from 1 to 2 with aqueous hydrogen chloride;
- c. cooling the mixture produced in step (b) gradually to bring the temperature from 30°C to 5°C - 0°C; and
- d. isolating and drying the sertraline hydrochloride to obtain Form V.

18-32. (Canceled)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON BROOKS whose telephone number is (571)270-7682. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, DANIEL SULLIVAN can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CB/

/Daniel M Sullivan/  
Supervisory Patent Examiner, Art Unit 1621